Informed consent for biobanking: consensus-based guidelines for adequate comprehension

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Abstract

Purpose—Federal regulations and best practice guidelines identify categories of information that should be communicated to prospective biobank participants during the informed consent process. However, uncertainty remains about which of this information participants must understand to provide valid consent.

Methods—We conducted a Delphi process to define "adequate comprehension" in the context of biobanking consent. The process involved an iterative series of 3 online surveys of a diverse panel of 51 experts, including genome scientists, biobank managers, ethics and policy experts, and community and participant representatives. We sought consensus (greater than 70% agreement) concerning what specific details participants should know about 16 biobank consent topics.

Results—Consensus was achieved for 15 of the 16 consent topics. The exception was the comprehension needed regarding the Genetic Information Nondiscrimination Act.

Conclusions—Our Delphi process was successful in identifying a concise set of key points that prospective participants must grasp to provide valid consent for biobanking. Specifying the level of knowledge sufficient for individuals to make an informed choice provides a basis for improving consent forms and processes, as well as an absolute metric for assessing the effectiveness of other interventions to improve comprehension.

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Keywords

Informed consent; comprehension; biobanking; Delphi process; research ethics

INTRODUCTION

Biobanks and biospecimens are critical components of much medical and translational research[1]. Numerous biobanking efforts are underway around the world[2, 3], but informed consent for the collection and storage of materials for future research use remains a challenge. This challenge will be magnified if proposed changes to federal regulations governing human subjects research move forward, as these would require consent for research use of biospecimens, regardless of whether they are initially collected for clinical or research purposes[4].

The goal of informed consent is to enable competent individuals to decide for themselves whether to participate in research. However, obtaining consent is not simply a matter of disclosing information; promoting comprehension is integral to ensuring that the individual's decision is actually "informed". Valid consent can be critical for protecting the rights and welfare of individuals whose biospecimens are used in research, with recent headlines providing a stark reminder of what can otherwise happen[5–8].

For research involving biobanking, government regulations and best practice guidelines identify key categories of information that should be communicated to prospective participants during the consent process[9, 10]. But little attention has been paid to identifying which of this information prospective participants must grasp to demonstrate adequate understanding. Although participants would perhaps ideally understand every detail of the information deemed important for inclusion in a consent form, such comprehensive knowledge is not necessary to give valid consent[11, 12].

As long as the threshold for adequate comprehension remains unspecified, researchers may fail to identify participants whose consent is not valid or, conversely, deny participation to individuals whose understanding is, in fact, adequate. Significantly, uncertainty as to what constitutes adequate comprehension also undermines efforts to evaluate the sufficiency of consent forms and processes, and the development and assessment of interventions to improve them. To address this gap, we conducted a Delphi process with a diverse panel of experts to define "adequate comprehension" in the context of informed consent for biobanking.

MATERIALS AND METHODS

The Delphi method is an iterative process involving a series of surveys (or 'rounds') to gather opinions and seek consensus from a panel of experts[13–18]. The results of one survey are used to construct the next, and panelists are asked to consider their subsequent responses in light of previous rounds' results. The absence of an obligation to meet in person lessens constraints on group size and composition. Panelists can be allowed substantial time to

consider evidence and reflect upon their answers, and the anonymous nature of the process ensures that a single influential panelist will not have a disproportionate impact.

Selection of Experts

Our main consideration in selecting the size and composition of our panel was to ensure the results would be regarded by others as reflecting the consensus of experts representing a range of relevant perspectives. To that end, we recruited panelists from existing committees and consortia that play a leading role in biobanking and human research protections in the U.S. We identified and invited panelists based on recognized expertise in (a) biobanking operations/research; (b) ethics/policy in human subjects research; and/or (c) community/ participant perspectives. The latter included members of community advisory boards for major U.S. biobanks, as well as scholars with extensive experience studying community and participant attitudes and opinions. We confirmed prospective panelists' expertise through an "about you" questionnaire. Those who rated themselves less than 'somewhat familiar' with informed consent for biobanking were deemed ineligible.

We compensated panelists $200 per round; those who did not complete a round were not included in subsequent rounds.

Procedures

We conducted 3 online surveys to define "adequate comprehension" for biobanking consent. The surveys were structured around model consent language (Appendix S1), adapted from established sources[19–21] and purposely containing ample detail to accommodate a range of opinions about comprehension.

Across all surveys, panelists' task was to review the model language and, for each of the 16 sections, indicate the minimally correct answer if a prospective participant were asked to explain that topic in his own words. Specifically, we asked panelists to identify the answer that reflects the minimum understanding necessary to provide valid consent. We asked them to imagine that, during the consent process, the study coordinator would compare the participant's answer to the panelist's answer. If the participant's answer was missing key elements of information, the coordinator would review that topic with him in an effort to improve understanding. If the person was still unable to provide the minimally correct answer, he would not be allowed to participate.

A detailed description of the content and analysis of each survey is provided in Appendix S2. In summary, our approach moved from more qualitative elicitations in early rounds to more quantitative elicitations in later rounds. Results from each were provided to panelists and used as the basis for subsequent surveys. The Round 3 survey was explicitly designed to assess consensus quantitatively. Panelists were shown the model consent language, together with one statement per section of what prospective participants would need to say if asked to explain that topic. We constructed this statement to reflect the greatest degree of agreement developed through the prior rounds. Panelists were asked to rate on a 4-point scale how much they agreed or disagreed that the statement generally represented adequate comprehension. There are no established criteria for defining consensus in a Delphi process,

with suggestions in the literature ranging from 51% to 80% [17]; we selected 70% agreement as our predetermined threshold.

The Duke University Health System Institutional Review Board (IRB) deemed this study exempt (45 CFR 46.101(b)(2)). The surveys were implemented online between February–October 2013 using Qualtrics software.

RESULTS

Panelist Characteristics

We invited 61 individuals to participate on the panel. Of these, 3 were determined ineligible, 5 did not respond, 1 was unable to participate, and 1 declined. Those enrolled (n=51) represented a wide range of expertise and considerable familiarity with biobanking consent (Table 1). We maintained a high participation rate throughout the study, with 47 (92% of enrolled) completing all three rounds.

Early Rounds

In Round 1, we identified a total of 238 substantive elements of information in panelists' qualitative responses regarding which specific details prospective participants must grasp. Eighty-four of these elements were mentioned by at least 20% of panelists, our threshold for inclusion in the next survey. In Round 2, of the 84 elements of information we incorporated, 51 (61%) were endorsed by fewer panelists and 33 (39%) were endorsed by more panelists compared to Round 1. In general, panelists' Round 2 responses moved in the direction suggested by our Round 1 results, *i.e.,* elements less often endorsed in Round 1 tended to be endorsed even less often in Round 2, and vice versa (Appendix S3). Table 2 provides additional details regarding both section- and element-level results from these early rounds.

Final Round

In Round 3, consensus was achieved on 15 of the 16 consent topics (Table 3). There was near unanimity on 6 topics, for which more than 90% of panelists agreed or strongly agreed that the statement given represented adequate comprehension. For 5 topics, more than 80% agreed or strongly agreed with the statement provided.

Three topics exceeded our consensus threshold of 70% agreement, but with slightly more variation of opinion (Certificates of Confidentiality, Blood Draw, Access to Biospecimens/ Data). For each of these, panelists who disagreed that the statement represented adequate comprehension most often indicated that it reflected less than prospective participants need to know.

One other topic—Risk—met our consensus threshold, achieving 70% agreement. Most panelists who disagreed indicated that the statement reflected less than prospective participants need to know, although a nontrivial fraction said it reflected *more* than required for valid consent.

The topic for which consensus was not achieved was the Genetic Information Nondiscrimination Act (GINA). Early round results for this topic were disparate and thus it

was the only one for which we presented 2 separate statements in Round 3. Over half (53%) of panelists agreed with the first option, "There is nothing in this section prospective participants must understand." A slightly larger proportion (60%) agreed that the second option, "There is a law against discrimination based on my information", represented adequate comprehension—although 26% felt it reflected less than participants need to know and 15% felt it reflected more. Panelists' comments at the end of the survey suggested that these differences may be due to skepticism about GINA itself, as well as the opinion that participants should understand the limitations of the law[22] (Table 4).

Panelists' comments about the Delphi process were substantially positive (Table 4). Many characterized the experience as enjoyable and thought-provoking, and the process as well-organized and easy to follow. A few provided critiques, *e.g.,* about the length of the process, a preference for more qualitative input in Round 3, and of Delphi techniques in general as 'academic'. One wondered whether focusing on one consent topic at a time may have led to an overestimate of what participants need to know. However, most panelists looked forward to the final results with anticipation that they would be useful to the field.

DISCUSSION

Valid informed consent requires that individuals understand and voluntarily agree to participate in research[23]. Yet numerous studies have shown that participants in a variety of settings—including biobanking[24–26]—fail to grasp important aspects of the research to which they consented. Many commentators identify one source of the problem as equating informed consent solely with the requirement to disclose information[27–29]. Disclosure is indeed a key aspect of informed consent, and federal regulations and best practice guidelines provide lists of topics that should be covered in consent forms. Although these are useful starting points, they are not identical to the elements that individuals must understand to give valid consent[23]. As stated by Appelbaum[12]:

> Consensus is needed on the question of what information must be understood and to what degree before subjects can be said to have adequate comprehension… Research regulations generally elide this problem with lists of information to be disclosed as if all bits of data were equivalent. It is completely unrealistic, however, to expect research subjects to understand everything they are told, given the scope of most consent forms and the inherent complexity of projects, and some of what is communicated is clearly quite tangential to comprehension of the study itself. [p.2]

Without consensus on which information is most crucial for participants to understand, it is difficult to operationalize researchers' ethical obligation to ascertain comprehension[30] or to make progress on improving forms and processes to ensure valid consent[31].

We attempted to meet this need in biobanking consent by engaging a diverse group of experts in a systematic process to define "adequate understanding". Our results reflect a high degree of consensus on a relatively small number of key points that prospective participants must grasp to provide valid consent. This outcome was achieved despite significant initial variability of opinion on the panel, which included genome scientists, biobank managers, ethics and policy experts, and community/participant representatives. Through a series of

interrelated surveys, in which panelists were able to consider results from prior rounds and perhaps think about informed consent in new ways (Table 4), there was clear movement toward consensus and ultimately agreement. It is not uncommon for empirical studies of ethical issues to reveal discordant views among stakeholders—including our own research on the content of biobank consent forms[32]. Our present findings suggest there is reason for optimism that common ground can be reached upon further work and reflection.

GINA was the only consent topic for which consensus was not achieved. Early round opinions were especially varied, leading this to be the only topic for which 2 statements were presented for consideration in the final survey. It is possible that the lack of consensus for GINA in the final round was due in part to having two options to evaluate rather than one. Pending further research, whether knowledge of GINA is essential for valid consent will be a matter of investigator judgment.

Interpretation of our results is subject to several limitations. First, our panel lacked cultural diversity. Subject matter expertise was the primary inclusion criterion and we identified panelists based on membership in existing committees and consortia; thus the cultural diversity of the panel reflects that of these underlying entities. Second, we asked panelists about existing model consent language for a general, non-disease-specific biobank such as might be established at any academic medical institution. Biobanks that focus on a particular disease or that are established within special populations[5] may require different levels or types of understanding for valid consent. In general, investigators looking to assess comprehension may choose to tailor our results to fit their study context; interim findings from our earlier rounds (Table 2) suggest candidates for additional elements of information that some may deem essential. Third, our study was conducted in the U.S., with panelists and consent language based on the U.S. context. Although further work is needed, our results may still be useful other settings, as approaches to biobanking are not only similar around the world but being harmonized in order to enable global data sharing[33].

The goal of our study was not to identify which information should be disclosed to prospective biobank participants, but rather which details among those disclosed are essential for participants to understand. We believe our results may be useful in 3 ways:

- **Improve consent forms**: Consent forms must meet federal regulatory requirements; in addition, they should be responsive to best practice guidelines and focus on information most important to prospective participants[32, 34]. Within these parameters, our results may be helpful to organize and format forms to highlight the most essential information; less important details may be candidates for removal when not needed for another reason, or moved to supplemental material. Table 3 items could also serve as an introductory 'executive summary' (Table 5) to a consent form or provide the basis for a brief, standard form as has been advocated[35, 36].

- **Improve consent processes**: Similarly, consent processes—which will increasingly be undertaken in a variety of scalable ways—could be directed to focus on effectively communicating the most crucial information. Table 3 items

could serve as the basis for developing tools and assessing comprehension in practice (*e.g.,* through a teach-back tool, online quiz[37, 38]).

- **Facilitate research on biobanking consent:** Lack of a common definitions and standardized tools for assessing understanding have led to "conceptual and methodologic chaos"[12] in studies of research participant understanding[31] and interventions to improve informed consent[38]. Our results help remedy this for biobanking; Table 3 items provide an absolute metric of adequate understanding—an improvement over relative assessments of which intervention produces better scores than another without know whether either is adequate.

Next steps in our own program of research include using these results to develop practical ways to assess comprehension, and to employ these tools to determine the effect of a simplified biobanking consent form on comprehension. Further areas for future research include potentially using similar steps and methodologies to improve informed consent in other contexts (*e.g.,* Phase III clinical trials). Delphi techniques explicitly make use of expert opinion, *i.e.,* involve individuals with substantial existing knowledge of the topic area. Additional research could make use of deliberative democracy methods[39–41] to elicit informed and well-considered opinions about consent comprehension from the general public.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Characteristics of Delphi panelists

	Enrolled n=51 n (%)	Round 1 n=49 n (%)	Rounds 2–3 n=47 n (%)
Years in current position:			
Mean	10.5	10.5	10.5
Range	2–39	2–39	2–39
Familiarity with informed consent for biobanking ±			
Somewhat familiar	3 (6)	3 (6)	3 (6)
Familiar	11 (22)	10 (20)	10 (21)
Very familiar	37 (73)	36 (73)	34 (72)
Major Areas of Expertise §			
Bioethics	22 (43)	22 (45)	22 (47)
Genetics	21 (41)	21 (43)	20 (43)
Patient, research participant, or community perspectives	17 (33)	17 (35)	16 (34)
Medicine or Nursing	12 (24)	11 (22)	10 (21)
Epidemiology / Public health	11 (22)	11 (22)	10 (21)
Social Sciences	10 (20)	9 (18)	9 (19)
Law	5 (10)	5 (10)	5 (11)
Other	13 (25)	12 (24)	12 (26)
Academic Degrees Obtained §			
BA/BS	24 (47)	24 (49)	22 (47)
MA/MS	20 (39)	19 (39)	19 (40)
MPH/MSPH	8 (16)	8 (16)	8 (17)
JD	6 (12)	6 (12)	5 (11)
PhD	26 (51)	26 (53)	26 (55)
MD	10 (20)	9 (18)	8 (17)
Other	3 (6)	3 (6)	2 (4)
Age			
30–39	5 (10)	5 (10)	5 (11)
40–49	14 (27)	14 (29)	14 (30)
50–59	19 (37)	17 (35)	17 (36)
60–69	11 (22)	11 (22)	10 (21)
70+	2 (4)	2 (4)	1 (2)
Sex			
Female	33 (65)	33 (67)	32 (68)
Male	18 (35)	16 (33)	15 (32)
Race §			
White	45 (88)	43 (88)	41 (87)
Asian	3 (6)	3 (6)	3 (6)
Black	2 (4)	2 (4)	2 (4)

	Enrolled n=51 *n (%)*	Round 1 n=49 *n (%)*	Rounds 2–3 n=47 *n (%)*
American Indian/Alaska Native	1 (2)	1 (2)	1 (2)

[±]Respondents who rated themselves as 'not too familiar' or 'not at all familiar' were deemed ineligible

[§]Respondents were allowed to choose more than one

Table 2

Summary of early round results[++]

Consent Form Topic *(% who identified nothing important in Round 1/Round 2)*	Interim Statement of Understanding [% who endorsed element in Round 1/Round 2]
Biobank Purpose *(8/0)*	"The purpose of this project is to **collect** [47/64] and **store** [57/81] **samples** [78/100] and **health information** [49/74] for use in **future** [51/81] **genetic** [29/26] **research** [76/100]."
Blood Draw *(8/2)*	"You are going to draw a **small amount** [29/23] of **blood** [92/98] from my **arm** [24/26]. From this blood, you will be able to get **DNA** [20/23]."
Collection of Information *(2/0)*	"You will ask me some **basic information** [57/79] about myself and my **family history** [31/17] and will **contact me** [57/83] no more than **once a year** [45/26] to update this information. You will also collect information from my **medical records** [84/100] **from time to time** [33/17]. These things will happen for **as long as my sample is stored in the biobank** [33/19]."
Duration of Storage *(14/6)*	"My sample and information will be **stored** [65/89] and **used for research** [29/51] **forever** [63/94] unless I decide to **stop taking part** [61/94] or you **close the biobank** [22/17]."
Access to Biospecimens / Data *(8/6)*	"Many **other researchers** [45/36] from all over the **world** [22/21] may **study** [78/94] my samples and information. There will be a **review of each request** [24/21]. You will not give researchers information that could **identify me** [53/64] without my **permission** [24/17]."
Recontact *(10/4)*	"**Researchers may want to contact** [31/21] me for **more information** [35/21] or to ask me to participate in **more research** [51/96]. If this happens, someone from the **biobank will contact** [59/96] me first to **make sure it is OK** [22/4]. I won't be contacted about more than **four studies a year** [22/2], and for each one **I can choose** [20/6] whether or not to take part."
Large-Scale Data Sharing *(16/4)*	"Some of my information, including **genetic** [35/32] information, might be put into a **database** [49/79] to be **shared** [27/36] with others **outside the biobank** [22/21] for use in research. Information that could **identify me** [29/36] will not be put into a database, but there is still a **small chance** [41/77] that someone could trace my information **back to me** [67/96]. Researchers always have a **duty to protect** [22/21] my information."
Risks *(6/4)*	"There are some risks associated with the **blood draw** [29/26]. There is also a **small chance** [47/53] that someone could get **access to information about me** [51/96] and **use it against me** [39/49] in some way. Things researchers learn could also be used to support **harmful ideas about groups** [22/13] of people. **You will do everything you can** [29/19] to **prevent my information from being used in harmful ways** [20/11]."
Confidentiality Protections *(33/28)*	"You will take **many steps to protect my privacy** [43/72], including not giving out information that could **identify me** [20/13]."
Genetic Information Nondiscrimination Act (GINA) *(37/32)*	"There is a **law** [45/68] that **protects me** [33/38] from **discrimination** [51/68] by **health insurers** [37/38] and **employers** [35/38] based on my **genetic** [31/38] information. However, the law **does not protect me** [39/60] from genetic discrimination by **life insurance** [22/11] and **long term care insurance** [20/11] companies."
Certificate of Confidentiality *(45/68)*	"You have a **Certificate** [20/28] that says that you **do not have to give out my personal information** [22/32]. However, under some circumstances, you **may still have to disclose** [29/34] my information to certain authorities."
Potential Benefits *(10/6)*	"I should **not expect to benefit** [90/94] **directly** [59/28] from this research. It may **help other people** [20/13]."
Costs and Payments (Commercialization) *(24/19)*	"It **won't cost** [37/19] me anything to participate in the biobank. You will give me a $25 **gift card** [35/26] for participating. Research done using my sample might someday lead to the development of a **product** [39/30] that could be sold. Although **others may profit** [31/6] from these products, I will **not get any money** [55/81] if this happens."
Return of Results *(6/2)*	"I **should not expect to get individual results** [76/98] back from this research, unless you find something **important to my health** [63/49]. If that happens, you will **contact me** [53/49] to see if I **want to learn more** [22/11]. **Research is not the same as medical care** [29/11]."
Discontinuing Participation *(14/4)*	"I have the **right to leave** [76/96] the project **at any time** [55/19]. However, I **cannot withdraw or get back** [65/79] samples and information from studies that have already begun."
Questions or Problems *(27/28)*	"There is a **phone number** [24/11] in the form I **can call** [67/72] if I have **questions or want more information** [63/72]."

[++]Results are displayed using the most detailed statement presented in the Round 2 survey, which incorporate elements endorsed by at least 20% of panelists in Round 1

Table 3

Final round results (n = 47)

Consent Form Topic	Adequate comprehension? [†] Agreed n (%)	Disagreed [‡] Too little n (%)	Too much n (%)
Biobank Purpose			
"The purpose of this project is to collect and store samples and health information for use in future research."	**41 (87)** **	6 (13)	0 (0)
Blood Draw			
"You are going to draw blood from me."	**35 (74)** **	12 (26)	0 (0)
Collection of Information			
"You will ask me some basic information and will contact me to update this information. You will also collect information from my medical records."	**46 (98)** **	1 (2)	0 (0)
Duration of Storage			
"My sample and information will be stored forever unless i decide to stop taking part."	**46 (98)** **	0 (0)	1 (2)
Access to Biospecimens / Data			
"Researchers may study my samples and information. You will not give researchers information that could identify me."	**35 (74)** **	11 (23)	1 (2)
Recontact			
"Someone from the biobank may contact me about participating in additional research."	**41 (87)** **	5 (11)	1 (2)
Large-Scale Data Sharing			
"Some of my information might be put into a database. There is a small chance that someone could trace my information back to me."	**39 (83)** **	5 (11)	3 (6)
Risks			
"There is a risk that someone could get access to information about me."	**33 (70)** **	11 (23)	3 (6)
Confidentiality Protections			
"You will take many steps to protect my privacy."	**43 (91)** **	2 (4)	2 (4)
Genetic Information Nondiscrimination act (GINA)			
"There is a law against discrimination based on my information."	**28 (60)**	12 (26)	7 (15)
Alternate: There is nothing in this section a prospective participant must understand to give valid consent.	**25 (53)**	*na*	*na*
Certificate of Confidentiality			
There is nothing in this section a prospective participant must understand to give valid consent.	**36 (77)** **	*na*	*na*
Potential Benefits			
"I should not expect to benefit from this research."	**45 (96)** **	1 (2)	1 (2)
Costs and Payments (Commercialization)			
"I will not get money from anything that is done using my sample."	**43 (91)** **	3 (6)	0 (0)

Consent Form Topic	Adequate comprehension? [†]	Disagreed [‡]	
	Agreed *n (%)*	**Too little** *n (%)*	**Too much** *n (%)*
Return of Results			
"I should not expect to get individual results back from this research."	**40 (85)**[**]	6 (13)	0 (0)
Discontinuing Participation			
"I have the right to leave the project. However, i cannot withdraw or get back samples and information from studies that have already begun."	**41 (87)**[**]	2 (4)	4 (9)
Questions or Problems			
"There is someone i can contact if i have questions or want more information."	**46 (98)**[**]	0 (0)	0 (0)

[†] Agreed or strongly agreed on 4-point scale in response to "How much do you agree or disagree that the statement above generally represents adequate comprehension of the consent topic?"

[‡] Among those who disagreed or strongly disagreed that the statement represents adequate comprehension, responses to question about whether the statement reflects more or less than a prospective participant needs to understand to provide valid consent.

[**] Reached consensus, pre-defined as ≥70% agreement

Table 4

Examples of panelists' comments on biobanking consent and Delphi process

Topic	Comment
Biobanking Consent-GINA	*Skepticism about legislation:*
	• Interesting result with respect to the GINA language—I do wonder if this is more a reflection of respondents' general skepticism about the legislation as a remedy for discrimination than an indication of preferences for comprehension?
	Need to know limitations:
	• With regard to [GINA], if it is important for participants to know that laws are in place to protect genetic information then they would also need to know that there are limitations to these laws.
	• I would prefer that this section be omitted entirely (*i.e.,* no reference to GINA in the consent document); however, if it is included, then participants should be required to recognize that there is a law seeking to protect them from discrimination … BUT that it has limitations.
Delphi Process	*Gained new insights:*
	• This survey (and the iterative process) has been fascinating and very informative. It has helped provide insight into the consent from the perspective of a participant.
	• This has been very interesting. When looked at closely, there were a number of areas which seemed important, that upon reflection do not seem to impact a patient's comprehension. This has helped me view the consent process from a new perspective.
	• It was interesting and enlightening. Really made me think about the whole purpose of informed consent and what subjects really need to know.
	Well-organized, easy to follow:
	• An easy and interesting process.
	• You provided the information in a clear and accessible way.
	• I really enjoyed the Delphi process. The instructional videos at the beginning of each stage were put together well and provided good instructions.
	Long process:
	• The process was quite long, and in places, tedious. It made me think about how participants feel about the informed consent process itself. I also realized all over again, how challenging many of the concepts are to convey to participants, and how challenging they are to understand, even for a person who regularly works with them.
	Over-estimate of knowledge needed for 'adequate' comprehension:
	• I was pleasantly surprised to see that most people did not want tons of disclosure, but I still fear that the clause by clause approach leads to too much product.
	Useful to the field:
	• This was fun. I feel as though progress is being made. I hope you rush preliminary results into publication, because IRBs and investigators are grappling with trying to streamline the biobank consent process right now.
	• I look forward to the final analysis and recommendations to apply as a standard.

Table 5

Example of consent form 'executive summary'

We would like to store some of your blood and health information in the Duke Biobank for use in research on health and disease. You can take part in this storage project or not. This consent form gives information to help you decide. Please read it carefully and take all the time you need to make your choice. Some of the most important things for you to know are:

- The purpose of this project is to collect and store samples and health information for use in future research.

- We will draw blood from you. We will ask you some basic information and will contact you to update this information. We will also collect information from your medical records.

- Your sample and information will be stored forever unless you decide to stop taking part.

- Researchers may study your samples and information. We will not give them information that directly identifies you.

- Someone from the Biobank may contact you about participating in additional research.

- Some of your information might be put into a database. There is a small chance that someone could trace your information back to you.

- We will take many steps to protect your privacy, but there is a risk that someone could get access to information about you. There is a law against discrimination based on your information.

- You should not expect to benefit from this research. You will not get money from anything that is done using your sample. You should not expect to get individual results back from this research.

- You have the right to leave the project. However, we cannot withdraw or get back samples and information from studies that have already begun.

- There is someone you can contact if you have questions or want more information.

Readability characteristics: Flesch-Kincaid grade level 7.3; Flesch-Kincaid reading ease 65.2 (test rates text on 100-point scale; the higher the score, the easier it is to understand); passive sentences 9%